

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

MAX WELLS,	§	
	§	
PLAINTIFF,	§	
	§	
vs.	§	CAUSE NO. A-06-CA-126-LY
	§	
SMITHKLINE BEECHAM	§	
CORPORATION,	§	
	§	
DEFENDANT.	§	

**DEFENDANT’S OPPOSITION TO PLAINTIFF’S MOTION TO EXCLUDE
A PORTION OF THE TESTIMONY OF
DEFENDANT’S WITNESS DR. GEORGE SANTOS**

INTRODUCTION

The plaintiff, Dr. Max Wells, has moved to exclude “a limited portion” of the proposed testimony of George Santos, M.D., one of the expert witnesses for the defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“GSK”).¹ As described below, Dr. Santos is a board-certified practicing psychiatrist and president-elect of the Texas Society of Psychiatric Physicians. Dr. Santos was retained to provide a psychiatric opinion about whether Requip, a Parkinson’s disease drug manufactured by GSK, caused Dr. Wells to become a pathological

¹ Although Dr. Wells states at the beginning of his motion that it is “limited to a single one sentence paragraph of the report and testimony related thereto” (Wells Mot. p. 1), his Prayer for Relief requests an order “excluding from the factfinder’s review *any* opinions by Dr. George Santos relating to the issue of whether the scientific literature supports or does not support a statement to a reasonable degree of medical certainty that Requip causes or contributes to gambling” (*Id.* p. 7; emphasis added). Regardless of the relief sought, Dr. Wells’ motion is unfounded for the reasons set forth in this Opposition.

gambler and lose millions of dollars.² Before formulating his opinion, Dr. Santos conducted an independent medical examination of Dr. Wells; searched published medical literature; and reviewed thousands of pages of materials, including medical and other records pertaining to Dr. Wells; deposition testimony of Dr. Wells, his family members and treating doctors; the reports of Dr. Wells' proposed expert witnesses; and published medical literature listed in his report. Dr. Santos concluded that (i) Dr. Wells did not meet the criteria for a diagnosis of pathological gambling, and (ii) it is not possible to conclude to a reasonable degree of medical certainty that Requip caused or contributed to Dr. Wells' gambling, in part because "[t]he scientific literature does not permit a statement to a degree of reasonable medical certainty that Requip causes or contributes to gambling" (Santos Report p. 7).

Dr. Wells has moved to strike the latter statement from Dr. Santos' report and to exclude any testimony by Dr. Santos regarding whether the scientific literature supports a statement that Requip causes or contributes to gambling (Wells Mot. p. 2). Oddly, Dr. Wells requests that this opinion be stricken *even though his own experts agree that the scientific literature does not establish that Requip causes pathological gambling*, as explained in GSK's *Motion for Summary Judgment as to Causation*. On this basis alone, the motion to strike Dr. Santos' opinion should be denied.

Moreover, Dr. Wells does not challenge, and thereby acknowledges, that Dr. Santos is qualified to testify regarding whether Dr. Wells became a pathological gambler and whether Requip caused or contributed to his gambling. Yet, Dr. Wells contends that Dr. Santos is not qualified to testify regarding the scientific literature because he "is neither a scientist nor a researcher; he is a practicing physician," and he does not have "experience in the publication,

² Pathological gambling is a psychiatric diagnosis set forth in the *Diagnostic & Statistical Manual of Mental Disorders – Fourth Edition – TR* ("DSM-IV-TR"). See DSM-IV-TR at 674.

study design or peer review of scientific literature” (Wells Mot. p. 2). Therefore, by his motion, Dr. Wells asks the Court to rule that a board-certified practicing psychiatrist who is licensed in the State of Texas and is president-elect of the Texas Society of Psychiatric Physicians is not qualified to testify about the scientific literature addressing a claimed cause of a psychiatric condition – pathological gambling.

Dr. Wells’ objections to Dr. Santos’ proposed testimony are unfounded. As discussed below, it is entirely appropriate for an otherwise-qualified practicing psychiatrist to review and express an opinion about scientific literature pertaining to whether a drug is capable of causing pathological gambling. Indeed, it is difficult to see how Dr. Santos could have fairly considered whether Requip caused or contributed to Dr. Wells’ gambling *without* considering the pertinent scientific literature. Furthermore, and contrary to Dr. Wells’ position, an otherwise-qualified expert witness does not have to be a researcher, or to have experience writing or reviewing scientific literature, to take such literature into account in forming an expert opinion. Dr. Wells’ motion should be denied in all respects.

BACKGROUND

A. Dr. Santos

Dr. Santos is a board-certified psychiatrist licensed in the State of Texas. He received all of his medical and general psychiatry training at the University of Texas Medical School at Houston. Dr. Santos has been in private practice as a psychiatrist since 1990, and since 1997 he has been Chief Medical Officer and Executive Medical Director of West Oaks Hospital. West Oaks is Houston’s largest and oldest private psychiatric hospital; it provides inpatient and outpatient services, including addiction services, to patients of all ages. In his positions at West Oaks, Dr. Santos both cares for patients and supervises all of the hospital’s medical staff and clinical operations. Dr. Santos also serves as a Senior Examiner for the American Board of

Psychiatry and Neurology, for which he examines candidates for board certification in psychiatry. He is currently the President-Elect of the Texas Society of Psychiatric Physicians (Santos Report, p. 1 and CV).

B. Dr. Wells' claim

Dr. Wells claims that he became a pathological gambler and lost millions of dollars as the result of his treatment with Requip. Two of Dr. Wells' three expert witnesses, Timothy Fong, M.D., a psychiatrist, and Ari Kalechstein, Ph.D., a psychologist,³ have provided expert reports in which they state that "Dr. Wells' pathological gambling behaviors were associated with his taking dopamine agonists" (Fong Report p. 31)⁴ and "the most likely explanation for Dr. Wells gambling behavior is the use of Requip" (Kalechstein Report p. 34).

C. Dr. Santos' opinion

GSK retained Dr. Santos to provide a psychiatric opinion "regarding Dr. Wells' claim that the medication Requip caused him to gamble pathologically resulting in large financial losses" (Santos Report p. 1). Dr. Santos concluded that (i) Dr. Wells did not meet the criteria for a diagnosis of pathological gambling, and (ii) it is not possible to conclude to a reasonable degree of medical certainty that Requip caused or contributed to Dr. Wells' gambling, in part because "[t]he scientific literature does not permit a statement to a degree of reasonable medical certainty that Requip causes or contributes to gambling" (*Id.* p. 7). Dr. Wells only challenges Dr. Santos' qualifications to reach conclusions regarding the scientific literature.

As he should, Dr. Santos considered Requip as one of the possible factors that may have contributed to Dr. Wells' gambling behavior. In so doing, he performed literature searches and

³ Dr. Wells' third expert witness is Stephen R. Saklad, Pharm.D., a pharmacist.

⁴ Contrary to this statement in his report, in his deposition testimony Dr. Fong effectively agreed that Dr. Wells did not meet the criteria for a diagnosis of pathological gambling: Dr. Fong acknowledged that such a diagnosis requires that an individual meet at least five of ten criteria specified in the DSM-IV-TR, but he identified only four criteria met by Dr. Wells. *See GSK's Daubert/Havner Motion* (p. 10, n. 10).

reviewed pertinent medical literature that suggests a possible association between treatment with dopamine agonists (the class of drugs that includes Requip) and pathological gambling. As shown by the list attached to Dr. Santos' report, he reviewed more than 30 published articles related to this issue. Having reviewed the pertinent medical literature in order to consider Requip's possible contributing role in Dr. Wells' gambling, Dr. Santos concluded that "[t]he scientific literature does not permit a statement to a degree of reasonable medical certainty that Requip causes or contributes to gambling" (Santos Report p. 7).

Dr. Wells' counsel deposed Dr. Santos for seven hours, covering 300 pages of testimony. Yet, counsel asked fewer than ten questions concerning Dr. Santos' opinion about the medical literature he reviewed (Santos' Depo. at 252-59). Now, having left Dr. Santos' opinion about the medical literature essentially unexplored, Dr. Wells seeks to preclude Dr. Santos' opinion without any legitimate basis.

D. Dr. Wells' motion

Dr. Wells contends that Dr. Santos is not qualified to express an opinion with respect to the state of the scientific literature as a component of his opinion concerning Dr. Wells' claim that Requip caused his alleged pathological gambling. Dr. Wells argues, in summary, that Dr. Santos is not qualified because he is a "practicing physician" rather than "a peer reviewer, scientific researcher or author of scientific literature" (Wells Mot. p. 2).

Not surprisingly in view of his role as a practicing psychiatrist, Dr. Santos has not published any peer-reviewed articles, served on a peer-review committee or been involved in study design (Santos Depo. at 256-58). According to Dr. Kalechstein – a psychologist who is not a medical doctor, much less a psychiatrist—the absence of such experience disqualifies Dr. Santos from making an assessment of the pertinent scientific literature because "[e]xperience and expertise in statistics and research methodology" and "[e]xperience and expertise as a peer

reviewer” are “essential when drawing conclusions from medical/scientific literature” (Kalechstein aff. ¶¶ 7-8). Dr. Wells argues further that Dr. Santos’ experience is insufficient because “he has never testified regarding whether scientific literature permits a statement to a reasonable degree of medical certainty that a particular medication causes or contributes to gambling” (Wells Mot. p. 3). Finally, Dr. Wells argues that, because Dr. Santos prepared “no written analysis” of the pertinent literature and “never tabulated the number of such articles,” his opinion with respect to the literature is based on nothing more than having “just looked through the articles . . . without applying any scientific methodology” (*Id.* pp. 3-4).⁵

ARGUMENT

DR. SANTOS IS QUALIFIED TO TESTIFY ABOUT THE MEDICAL LITERATURE RELEVANT TO DR. WELLS’ CLAIMED PSYCHIATRIC CONDITION.

In considering Dr. Wells’ claim that Requip caused his alleged pathological gambling, Dr. Santos, as he should, considered the medical literature bearing upon a possible association between treatment with dopamine agonists and gambling.⁶

Dr. Wells’ position is that an otherwise-qualified board-certified psychiatrist must have “expertise in statistics and research methodology” in order to assess pertinent scientific literature in forming an opinion about the cause of an individual’s claimed pathological gambling. This position has no legal basis, and none of the cases Dr. Wells cites supports such a conclusion. “The Fifth Circuit has held that medical testimony on the issue of specific causation satisfies

⁵ Dr. Kalechstein’s report included only one sentence concerning the published literature (Kalechstein Report p. 35), and Dr. Fong’s report included less than half a page (Fong Report p. 33). Drs. Fong and Kalechstein together cited only a handful of articles, in contrast to the more than 30 articles listed by Dr. Santos, and neither Dr. Fong nor Dr. Kalechstein provided any sort of “tabulation” of the literature. In its *Daubert/Havner Motion*, GSK does not challenge the opinions of Dr. Fong or Dr. Kalechstein on this basis.

⁶ As explained at p. 10 of GSK’s *Motion for Summary Judgment as to Causation*, general causation addresses whether a substance (*e.g.*, Requip) is capable of causing a condition (*e.g.*, gambling) in the general population, while specific causation addresses whether the substance caused that condition in a particular individual (*e.g.*, Dr. Wells).

Daubert if the doctor bases his opinion on an exam (or a review of medical record[s]), his experience, and a broad reading of the medical literature.” *Kelley v. American Heyer-Schulte Corp.*, 957 F. Supp. 873, 883 (W.D. Tex. 1997)(citing *Carroll v. Morgan*, 17 F.3d 787, 789-90 (5th Cir. 1994)); *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *33 (Tex. Dist. Harris County June 7, 1999) (“Specific causation testimony should normally be based on a ‘broad reading of the literature’ . . .”). Dr. Santos’ opinion regarding the scientific literature is part and parcel of his specific causation opinion. It is therefore contrary to law and inconsistent for Dr. Wells to say on the one hand that Dr. Santos is qualified to address whether Dr. Wells was a pathological gambler and what caused his gambling, while claiming on the other hand that he is not qualified to read the medical literature pertinent to such an opinion and to state his conclusions with respect to that literature.

Dr. Wells is incorrect in arguing that that an otherwise-qualified board-certified psychiatrist must be a “scientist” or a “researcher” in order to express an opinion based, in part, on a review of scientific literature. Just this month, in *Abilene Independent School District v. Marks*, 2008 WL 2612093 (Tex. App. – Eastland July 3, 2008, no pet. h.), the court rejected a challenge to a treating orthopedic surgeon’s testimony on both general and specific causation, even though the surgeon’s general causation testimony was based solely on his review of medical literature. *Id.* at *8. Dr. Wells is also incorrect in arguing that, because Dr. Santos has not previously testified regarding scientific literature, he is not qualified to review and assess such literature in forming an opinion regarding the claim that Dr. Wells’ gambling was caused by Requip. *See id.* at *7 (“Nor did the fact that Dr. Cooke had not previously testified as an expert witness disqualify him from testifying as an expert witness in this case”). Nor is it necessary for a qualified expert like Dr. Santos to have engaged in independent research or publication in order

to address other experts' research within his area of expertise. As explained in *Garcia v. BRK Brands, Inc.*, 266 F. Supp. 2d 566 (S.D. Tex. 2003):

Certainly an expert need not conduct "hands-on" testing in every case. Rule 702 simply requires that scientific testimony be "ground[ed] in the methods and procedures of science," and that when an expert testifies in court, she adheres to "the same level of intellectual rigor" that the expert would use in the regular course of her professional work. Thus, an expert may base his theories or conclusions on the research of other experts if he can demonstrate that he has done so reliably. (*Id.* at 576; citations omitted.)

A Texas federal court rejected arguments similar to Dr. Wells' arguments here in *Avance v. Kerr-McGee Chemical LLC*, 2006 WL 4108454 (E.D. Tex. Nov. 30, 2006), in which the plaintiffs sought to exclude a defense oncologist's testimony that their cancers were not caused by exposure to creosote, on the ground that he "has done no independent research on the biological effects of creosote . . . he has never treated anyone for creosote related injuries; he has never been retained as an expert in any prior case related to creosote; he has never sought to analyze the chemical makeup of creosote . . . he has never participated in any epidemiological studies concerning creosote or its constituents, nor has he ever participated in any toxicological studies concerning creosote . . ." *Id.* at *5. The court held:

. . . Plaintiffs' complaints do not warrant exclusion of [the expert's] testimony. Included in [the expert's] report is a list of all the publications that he relied upon in reaching his opinions He consulted authoritative scientific studies and literature about cancer causation, analyzed the plaintiffs' medical records, and, relying upon his extensive training and expertise, used the generally accepted methodology in his field to develop opinions about the specific causes of the plaintiffs' cancers. (*Id.*; emphasis added.)

So too here, Dr. Santos analyzed Dr. Wells' medical records; the deposition testimony of Dr. Wells, his treating physicians and members of his family; the reports of Dr. Wells' experts; and the pertinent scientific studies and literature, and he relied on his extensive training and expertise as a board-certified practicing psychiatrist to develop an opinion with respect to

Dr. Wells' claim that Requip caused his alleged pathological gambling. Dr. Santos is fully qualified to review and draw conclusions about scientific literature pertinent to that issue.

Dr. Wells' remaining argument – namely, that Dr. Santos did not prepare any “written analysis” or “tabulation” of the articles he read – is not addressed to his qualifications and is not a basis for Dr. Wells to ask the Court to exclude Dr. Santos' testimony. It is in any event unclear what sort of “written analysis” or “tabulation” Dr. Wells claims Dr. Santos was required to prepare in order to demonstrate that his review amounted to more than “just look[ing] through articles” (Wells' Mot. pp. 3-4).

CONCLUSION AND PRAYER

For the reasons stated above, Dr. Wells' motion to exclude a portion of Dr. Santos' testimony should be denied. To do otherwise would require the Court to accept Dr. Wells' unfounded position that a board-certified practicing psychiatrist (who is also president-elect of the Texas Society of Psychiatric Physicians and who administers board certification examinations for psychiatry) is not qualified to read and formulate an opinion about medical literature pertinent to a possible cause of a specific psychiatric disorder.

Dated: July 31, 2008

Respectfully submitted,

FULBRIGHT & JAWORSKI L.L.P.

/s/ Marcy Hogan Greer

Stephanie A. Smith
State Bar No. 18684200
Stacey A. Martinez
State Bar No. 13144575
Marcy Hogan Greer
State Bar No. 08417650
600 Congress Avenue, Suite 2400
Austin, Texas 78701-2978
Telephone: (512) 474-5201
Facsimile: (512) 536-4598

PHILLIPS LYTLE LLP

Cindy K. Bennes
Paul K. Stecker
Suite 3400, One HSBC Center
Buffalo, New York 14203
Telephone: (716) 847-8400
Facsimile: (716) 852-6100

*Counsel for Defendant SmithKline Beecham
Corporation d/b/a GlaxoSmithKline*

CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of July, 2008, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following:

Tom Alleman
WINSTEAD P.C.
5400 Renaissance Tower
1201 Elm Street
Dallas, Texas 75270

David Morris
WINSTEAD P.C.
401 Congress Avenue
Suite 2100
Austin, TX 78701

Counsel for Plaintiff

/s/ Marcy Hogan Greer
Marcy Hogan Greer